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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,284	02/07/2005	Gesine Schliecker	I-2002.001 US	5686

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INTERVET INC.
PATENT DEPARTMENT
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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,284	SCHLIECKER ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 7/9/04 fails to comply with 37 CFR 1.98(a)(2), which requires a **legible copy of each cited foreign patent document; each non-patent literature publication** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

2. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claim does not further limit instant claim 11 to which it depends as azagly nafarelin is not a derivative or buserelin.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Krone et al. (US 5,391,696).

5. Krone et al. (US 5,391,696) teaches of a controlled release formulation (abstract) containing polytartrate polymer, such as (2',3'-(1',4'-diethyl)-L-tartyl poly-(2,3-O-isopropylidene)-L-tartrate), buserelin and pharmaceutically acceptable excipients (example 11; column 10, lines 57-58).

6. It is respectfully pointed out that instant claims 1-11 and 13 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krone et al. (US 5,391,696) in view of Suzuki et al. (US 6,015,789) and further in view of

Remington's Pharmaceutical Science (**1990**, 18th ed, chapter 89, page 1652) and MacLean (US 2002/0094992A1).

9. Krone et al. (US 5,391,696) teaches of a controlled release formulation (abstract) containing polytartrate polymer, such as (2',3'-(1',4'-diethyl)-L-tartyl poly-(2,3-O-isopropylidene)-L-tartrate), buserelin and pharmaceutically acceptable excipients (example 11; column 10, lines 57-58). Krone et al. does not disclose the process for the preparation of a polytartrate tablet or the GnRH agonist nafarelin.

10. Suzuki et al. (US 6,015,789) discloses a pharmaceutical composition/tablet containing a GnRH agonist, such as buserelin or nafarelin, pharmacologically acceptable carrier, etc. for administration to a human being (column 97, lines 63-66; claim 2; column 98, lines 17-20).

11. Remington's Pharmaceutical Science (**1990**, 18th ed, chapter 89, page 1652) discloses that formulations for the time-delay of medication (controlled-release) are well known in the art and that one such formulation is that of a multi-layer tablet. These multi-layer tablets contain have at least two layers separated by a layer of inert material (lag layer) and are advantageous as incompatible drugs can be formed into a single tablet via separation of the layers. The tablets may be prepared by the single compression method of different granulations or via each granulation receives a precompression stroke prior to singlet tablet formation (column 1, paragraph 2-4).

12. MacLean (US 2002/0094992A1) discloses that the daily administration of a combination controlled release and immediate release formulation results in increased plasma concentration of an active agent (p3, [0046]; p4, [0058]).

13. At the time of the invention it would have been obvious to one ordinarily skilled in the art to generate/try/utilize a controlled release multi-layer tablet/formulation containing a GnRH agonist as it is well known in the art. Substitution of buserelin for nafarelin would be obvious as they are equivalent GnRH agonists. It would be advantageous to prepare the multi-layer tablets of Remington's Pharmaceutical Science with a combination of controlled release and immediate release layers to increase the plasma concentration of a GnRH agonist over time. In regards to the compression force, it is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
September 21, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER